the DBL report

Issue #16, July 2000

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

In this issue:

Change in Benefit Status

■ **EFFEXOR-XR** (venlafaxine HCl) (extended-release capsules) (WAY), available on the AHWDBL via Special Authorization (SA) since October 1998, will now be covered as an unrestricted benefit. A new goal in the treatment of depression would be to have patients achieve remission (absence of symptoms) as opposed to only eliciting a response. Data show that a dose of 150 mg/day of venlafaxine is necessary to promote remission in most patients. The XR formulation can provide the appropriate dose with a once-a-day administration at a lower cost compared to the use of two immediate-release (IR) tablets.

Please Note: **EFFEXOR** tablets (IR formulation), available since April 1996, will continue to be covered by SA according to the following criteria: "Consideration may be given on an exception basis, to those patients who experience clinically significant difficulties with the extended-release (XR) formulation of venlafaxine". This six month extension of coverage will facilitate physicians' transition of patients from EFFEXOR tablets to the XR formulation where appropriate; or will allow physicians to re-apply for SA for those patients unable to tolerate the XR formulation. Requests for new patients for EFFEXOR tablets (IR) will be subject to the new SA criteria starting July 1, 2000.

Highlights of New Products Added

■ **GLUCONORM** (repaglinide) (NNA) was added to the AWHDBL effective May 1, 2000. Repaglinide is a short-acting insulin secretagogue which is chemically unrelated to traditional sulphonylureas. It is absorbed rapidly from the GI tract and has a very short half-life. As a prandial glucose regulator, GLUCONORM has been shown to carry a lower risk of hypoglycemia particularly in patients with flexible life-styles.

■ **FLOVENT** (fluticasone propionate) **50 mcg MDI** (metered dose inhaler) (GLA) has been made available via SA according to the following criteria: "For the prophylactic management of steroid-responsive bronchial asthma in patients who are unable to use the Turbuhaler® dosage form of budesonide". Low dose fluticasone has been shown to have efficacy comparable to that of budesonide, which is available at a lower cost. However, patients who do not have sufficient inspiratory capacity to use the Turbuhaler® device needed for the administration of budesonide, will benefit from the availability of the MDI.

Please note: 1) **FLOVENT DISKUS 50 mcg and 100 mcg MDPI** (multi-dose powder inhaler) were not added due to cost considerations. 2) **FLOVENT 25 mcg MDI** was not added since the recommended dose for children >4 yrs of 2 inhalations BID can be delivered by 1 inhalation BID of the 50 mcg strength.

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Highlights of Products Not Added

■ **XENICAL** (orlistat) (HRL) is indicated in conjunction with hypocaloric diet for obesity management. Consultations with clinicians in Alberta regarding the place of XENICAL in the management of diabetes resulted in the conclusion that this drug is not of significant benefit. It is unlikely that the prescription of XENICAL for one year would affect the natural history of diabetes which is a progressive condition with a tendency for requiring increasing pharmacological therapy. No guidelines are available on when it is appropriate to discontinue treatment with XENICAL.

Highlights of Deferred Products

■ **EVISTA** (raloxifene HCl) (LIL) remains deferred pending further review by the ECDET. Data to support a protective effect of raloxifene on breast and uterine tissue as well as a significant effect on cardiovascular endpoints are encouraging, yet remain inconclusive. As a consequence, recommendations and decisions regarding reimbursement must be done only in the context of osteoporosis therapy. From the osteoporosis data, the effect of raloxifene on vertebral fractures is comparable to that of other agents already available. The ECDET wishes to wait for the results of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) evaluation of raloxifene that will encompass both primary and secondary prevention as well as the treatment of osteoporosis.

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■ **BAYCOL** 0.4 mg (cerivastatin sodium) (YNO) has shown efficacy comparable to that of pravastatin 40 mg at a lower cost.

■ **MONOCOR** (bisoprolol fumarate) (CRY) which is currently indicated for the control of hypertension, is priced comparably to the LCA price of other β-blockers listed. Data have shown slight therapeutic benefit and better tolerability, particularly in the elderly.

■ **OXEZE TURBUHALER®** (formoterol fumarate dihydrate) 6 mcg (AZE) will offer flexibility for dosing in children.

■ **PMS-TERBINAFINE** (PMS), fast-tracked for May 1, 2000, will bring significant savings to the program.

Expert Committee Profiles: Dr. Judith Baker

Dr. Judith Baker joined the Expert Committee in May 1999. She obtained her BSP (Pharmacy), M.Sc. (Pharmaceutics) and Ph.D. in Biological Psychiatry from the University of Saskatchewan. Dr. Baker is a member of numerous professional associations including the Alberta Pharmaceutical Association (APhA) of which she was President in 1990, the Canadian Pharmaceutical Association (CPhA), the Canadian College of Clinical Pharmacy, the Capital Health Region (CHR) Pharmacists Association and the Canadian College of Neuropsychopharmacology. Dr. Baker has been a member of and has chaired many committees including the APhA Regulatory Affairs Committee and the APhA Drug Schedules Committee. Dr. Baker has also held teaching appointments at the University of Alberta and the University of Aston (UK). In addition to practicing as a part-time community pharmacist, Dr. Baker is currently involved in many projects related to pharmacy practice through her consulting roles for the Alberta Wellnet Pharmaceutical Information Network, APhA, Alberta Medical Association (AMA), CPhA, Health Outcome Pharmacies, and Capital Health Authority. Dr. Baker currently chairs the APhA Practice Review Committee and is a member of the AMA Cognitive Impairment Clinical Practice Working Group and a member of the Alberta Wellnet Pharmaceutical Information Network Working Group. Dr. Baker's vision of the Alberta government-sponsored drug programs is that they should be comprehensive in terms of the range of drug therapies offered but must be administered in a fiscally responsible manner. Solutions will have to be found to the questions such as "Who will benefit most from treatment?" and "How can we afford to pay for the drug treatment?" that are posed by the new and extremely expensive "biotechnology" drugs.

Products Removed from the AHWDBL

■ Products containing pseudoephedrine have been removed from the AHWDBL as they are available as over-the-counter medications. They are: **BALMINAL DECONGESTANT** (oral syrup), **DRIXORAL N.D.** (sustained-release tablets), **ELTOR-120** (sustained-released tablets) and **ROBIDRINE** (tablets).

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